

FIBROMYALGIA TENS IN PHYSICAL THERAPY STUDY (FM TIPS)

SC MEETING – MAY 16-17, 2023

BRIEF OVERVIEW



Randomize by
PT clinic site –
TENS vs. no-
TENS



TENS applied
during activity –
in clinic and at
home



Data collected
at PT clinic visits
electronically
and over phone



CURRENT STATUS

36

PT Clinics selected
(6 Healthcare Systems)

153

Physical Therapists
Trained

27

Clinics
Active

561

Subjects Screened

247

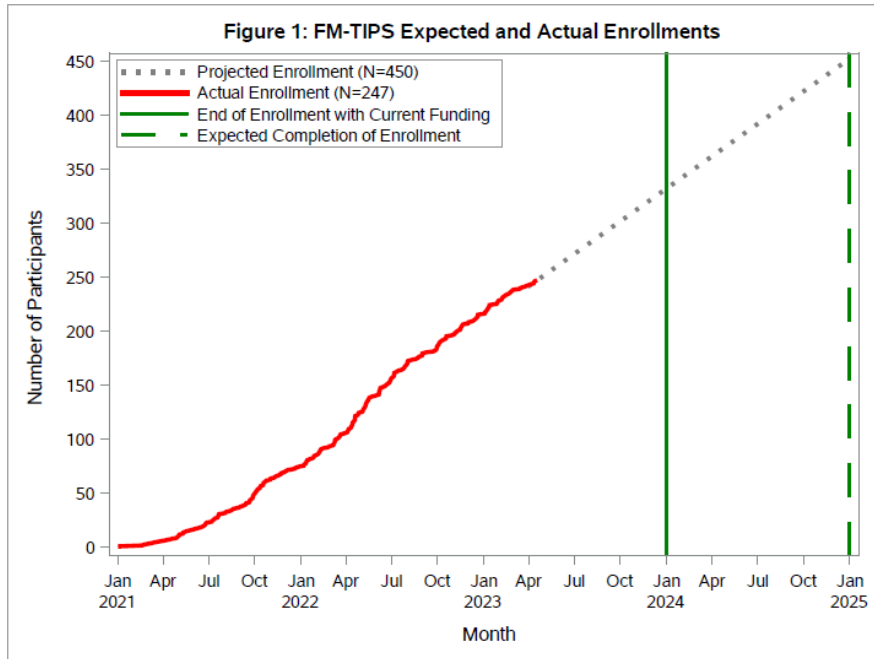
(55%)

Subjects Enrolled

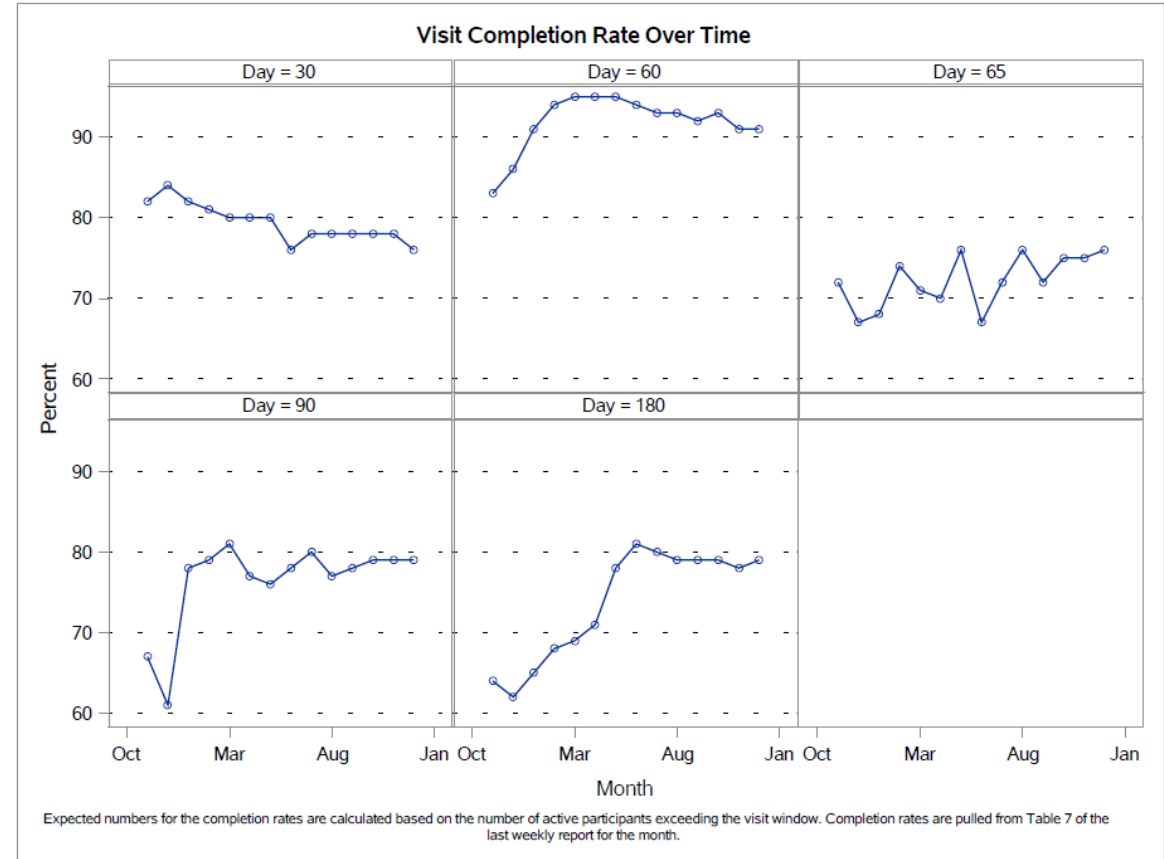
193

mITT

CURRENT STATUS



A sample size reduction from 600 to 450 with the approval of the NIH was implemented starting in April 2023.



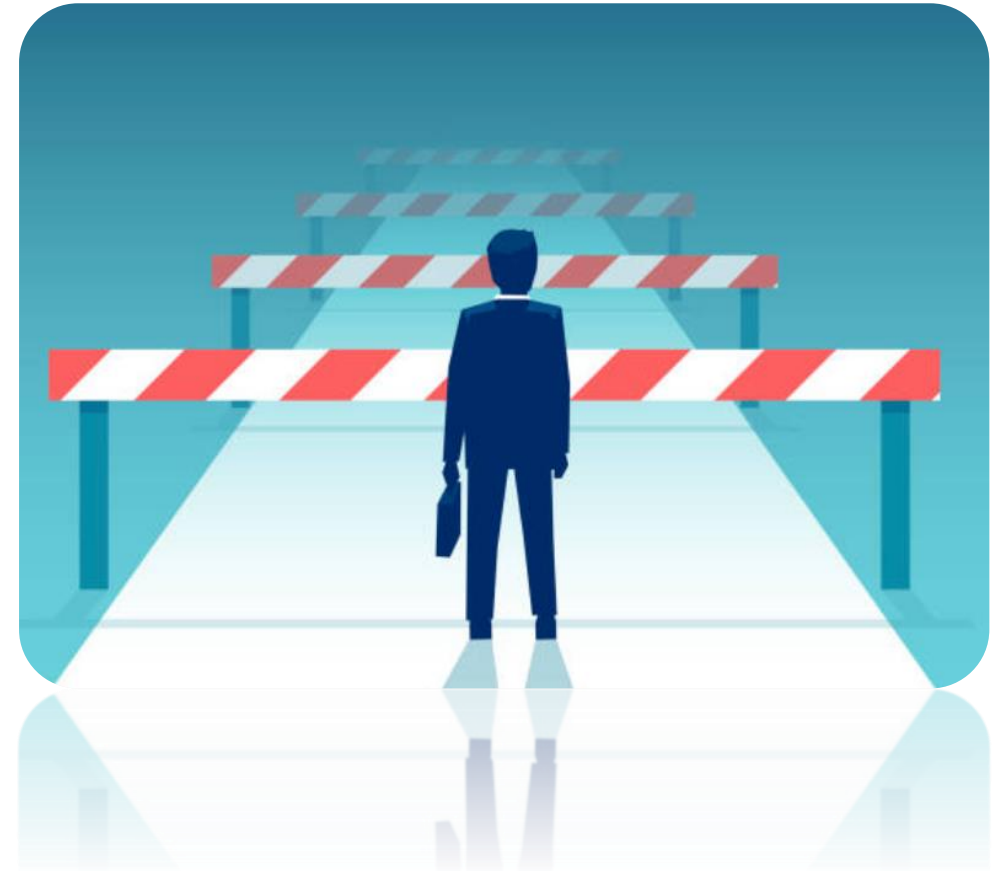
Barriers Scorecard

Barriers	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects			X		
Engagement of clinicians and health systems					X
Data collection and merging datasets			X		
Regulatory issues (IRBs and consent)		X			
Stability of control intervention	X				
Implementing/delivering intervention across healthcare organizations			X		

*Your best guess! 1 = little difficulty 5 = extreme difficulty

TOP CHALLENGES

- Recruitment
 - Limited care access for patients in rural areas
 - Keeping clinicians engaged for screening
 - Variability in screening and enrollment
- Retention
 - Participant changes e-mail or phone
 - Technology
 - internet access/smart phone
 - TENS application
- PT Outpatient Practice Staffing
 - Limited time available for study engagement
 - Concerns about lost reimbursement (although paying for this)
 - Reduced staffing
 - 17% vacancy rate for PT
 - office/front desk staff difficult to maintain
- Electronic Health Record Extraction



RECENT GENERALIZABLE LESSON LEARNED

- Study team contact with clinicians is critical for recruitment
- Clinicians welcome community engagement with referring providers and community partners
- Need to be creative with strategies to enhance clinician engagement, recruitment and retention of participants
- Not all strategies work for all clinics-each has an independent clinic culture which required individualized approach



DATA SHARING

- **What is your current data sharing plan and do you foresee any obstacles?**
 - Publish data in peer-reviewed journal
 - We have registered our study on ClinicalTrials.gov and on NIH HEAL Initiative, HEAL Data Platform.
 - We will share final data set to Inter-University Consortium for Political and Social Research (ICPSR) repository.
 - We have entered study level information on the CEDAR MetaData Center.
- **What information did the IRB require about how the data would be shared beyond the study in order to waive informed consent, if applicable?**
 - We are not waiving informed consent
- **What data you are planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?**
 - Individual Level Data, Group level data

DATA SHARING OBSTACLES



- No obstacles yet
- Working with the HEAL Data Platform

Thank you